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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,238	12/21/2001	Jayne E. Hastedt	0075.00	6678

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,238	HASTEDT ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *41-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amended claims 1-4 and 6-39 (21/09/2004) and claim 40 are under consideration.

2. Receipt of applicant's arguments and amendments filed on 21/09/2004 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 21/09/2004:

(i) the rejection of claims 1-40 under 35 U.S.C. § 112, second paragraph, and

(ii) the rejection of claims 1-32, 37-40 under 35 U.S.C. 102(b) as being anticipated by Nossal (1948).

4. Applicant's arguments filed on 21/09/2004 have been fully considered but were persuasive in part. The issues remaining as well as new issues are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

6a. Claims 1-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Nossal (1948) in view of Platz et al. (U.S. Patent No. 6,582,728).

Nossal teaches an acetone powder composition of whole blood as well as erythrocytes (see column 2, page 36, second para). Since IL-4 receptors are located on erythrocytes the whole blood powder as well as erythrocyte powder encompasses a powder composition comprising IL-4R, but does not teach the preparation of IL-4R as spray-dried particles.

Platz et al. teaches the advantages of using spray-dried powdered compositions of biologically active proteins such as insulin, interferons and interleukins, for administration by inhalation and discloses that powdered compositions exhibit a high level of stability (see column

4, lines 39-57; column 8, lines 61-67; columns 9-10 and Table I). Platz also teaches that these powdered drugs delivered to the lung are readily absorbed through the alveolar region directly into blood circulation (column 1, lines 25-40 and lines 64-67; column 2, lines 1-5). The reference teaches the dry powder has moisture content of less than 10% and usually below 5% by weight (%w) water (column 5, lines 54-59) and an aerosol particle size distribution of 0.3 to 5 μm (MMAD) (column 5, lines 27-54). The reference teaches pharmaceutical excipients such as amino acids, sugars and buffers, which are carriers of the powder (column 6, lines 65-68; column 7, lines 1-30). The reference also teaches particles having a MMAD of less than about 10 microns, a MMAD of less than about 5 microns, a MMAD of less than about 3.5 microns, and a MMAD of less than about 0.3 to 3 microns.

Therefore, it would have been prima facie obvious to one having ordinary skill in the art to modify the acetone powder composition comprising the IL-4R polypeptide of Nossal such that it includes obtaining spray-dried particles comprising IL-4R as taught by Platz et al., to obtain the known functions of spray-dried powdered compositions as per the teachings of Platz et al. which teaches the advantages of delivering spray-dried powders for pulmonary conditions. It would be obvious to obtain the IL-4R in powdered form to improve the therapeutic potential of IL-4R. One would have been motivated to obtain the IL-4R in spray-dried powdered form because Platz teaches that the spray-dried powdered form is free of liquid propellants such as CFC, HFC or carbon dioxide, the spray-dried powdered form can be easily manufactured and maintains a high percentage of pharmaceutical activity and exhibits a high level of stability (column 4, lines 39-57)

With respect to claims 3-9, 15-20, there would be a reasonable expectation of success for one of skill in the art to obtain the IL-4R in the active monomeric form. Therefore, the prior art references render obvious the instant claims.

6b. Claims 1-40 are rejected under 35 U.S.C. § 103 as being unpatentable over Mosley et al (US Patent No. 5,599,905) in view of Platz et al. (U.S. Patent No. 6,582,728).

Mosley et al. teaches that since IL-4 enhances secretion of IgE by stimulated B cells, the IL-4 receptor and soluble IL-4 receptor being useful in allergy therapy (see column 1, lines 24-36; column 3, lines 7-32). Mosley also teaches administration of the IL-4R by bolus injection and other suitable techniques (see column 16, lines 3-7), but does not teach the preparation of IL-4R as spray-dried particles.

Platz et al. teaches the advantages of using spray-dried powdered compositions of biologically active proteins such as insulin, interferons and interleukins, for administration by inhalation and discloses that powdered compositions exhibit a high level of stability (see column 4, lines 39-57; column 8, lines 61-67; columns 9-10 and Table I). Platz also teaches that these powdered drugs delivered to the lung are readily absorbed through the alveolar region directly into blood circulation (column 1, lines 25-40 and lines 64-67; column 2, lines 1-5). The reference teaches the dry powder has moisture content of less than 10% and usually below 5% by weight (%w) water (column 5, lines 54-59) and an aerosol particle size distribution of 0.3 to 5 μm (MMAD) (column 5, lines 27-54). The reference teaches pharmaceutical excipients such as amino acids, sugars and buffers, which are carriers of the powder (column 6, lines 65-68; column 7, lines 1-30). The reference also teaches particles having a MMAD of less than about 10

microns, a MMAD of less than about 5 microns, a MMAD of less than about 3.5 microns, and a MMAD of less than about 0.3 to 3 microns.

Therefore, it would have been prima facie obvious to one having ordinary skill in the art to modify the IL-4 R composition of Mosley et al. such that it includes obtaining spray-dried particles comprising IL-4R as taught by Platz et al., to obtain the known functions of spray-dried powdered compositions as per the teachings of Platz et al. which teaches the advantages of delivering spray-dried powders for pulmonary conditions. It would be obvious to obtain the IL-4R in spray-dried powdered form to improve the therapeutic potential of IL-4R. One would have been motivated to obtain the IL-4R in spray-dried powdered form because Platz teaches that the spray-dried powdered form is free of liquid propellants such as CFC, HFC or carbon dioxide, the spray-dried powdered form can be easily manufactured and maintains a high percentage of pharmaceutical activity and exhibits a high level of stability (column 4, lines 39-57)

With respect to claims 3-9, 15-20, there would be a reasonable expectation of success for one of skill in the art to obtain the IL-4R in the active monomeric form.

Therefore, the prior art references render obvious the instant claims.

Applicants argue that there must be some suggestion or motivation either in the references themselves or in the knowledge available to one of ordinary skill in the art to modify the reference or combine reference teachings and that the mere fact that the Platz et al. reference teaches a powdered form free of liquid propellants fails to provide the motivation to combine or modify Mosley teachings. However, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed

invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Platz et al teaches spray-dried particles of biologically active proteins (see columns 10-11, Table I) and the advantages of using such. Furthermore, the Mosley reference is being utilized in this rejection because it teaches an IL-4R composition. If the Mosley reference taught spray-dried particles comprising IL-4R, this rejection would be a 35 USC 102(b) rejection rather then a 35 USC 103 rejection.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

In response to applicant's argument that the Platz reference focuses on dispersible dry powders, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the Platz et al teaches spray-dried particles of biologically active proteins such as interleukins and interferons (see columns 10-11, Table I) and is therefore in the field of applicant's endeavor. In

response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Therefore, the prior art references render obvious claims 1-40.

6c. Claims 1-40 are rejected under 35 U.S.C. § 103 as being unpatentable over Lange (1999) in view of Platz et al. (U.S. Patent No. 6,582,728).

Lange teaches soluble IL-4 receptor administration for treatment of asthma, said IL-4R being administered as a spray in solution form (page 526, see column 1, lines 1-3). Lange also teaches administration of the IL-4R in a single dose (page 526, see column 2, last 2 lines; page 527, column 1, first line), but does not teach the preparation of IL-4R as spray-dried particles.

Platz et al. teaches the advantages of using spray-dried powdered compositions of biologically active proteins such as insulin, interferons and interleukins, for administration by inhalation and discloses that powdered compositions exhibit a high level of stability (see column 4, lines 39-57; column 8, lines 61-67; columns 9-10 and Table I). Platz also teaches that these powdered drugs delivered to the lung are readily absorbed through the alveolar region directly into blood circulation (column 1, lines 25-40 and lines 64-67; column 2, lines 1-5). The reference teaches the dry powder has moisture content of less than 10% and usually below 5% by weight (%w) water (column 5, lines 54-59) and an aerosol particle size distribution of 0.3 to 5 μm (MMAD) (column 5, lines 27-54). The reference teaches pharmaceutical excipients such as

amino acids, sugars and buffers, which are carriers of the powder (column 6, lines 65-68; column 7, lines 1-30). The reference also teaches particles having a MMAD of less than about 10 microns, a MMAD of less than about 5 microns, a MMAD of less than about 3.5 microns, and a MMAD of less than about 0.3 to 3 microns.

Therefore, it would have been prima facie obvious to one having ordinary skill in the art to modify the IL-4 R composition of Lange such that it includes obtaining spray-dried particles comprising IL-4R as taught by Platz et al., to obtain the known functions of powdered compositions as per the teachings of Platz et al. which teaches the advantages of delivering spray-dried powders for pulmonary conditions. It would be obvious to obtain the IL-4R in spray-dried powdered form to improve the therapeutic potential of IL-4R. One would have been motivated to obtain the IL-4R in spray-dried powdered form because Platz teaches that the spray-dried powdered form is free of liquid propellants such as CFC, HFC or carbon dioxide, the spray-dried powdered form can be easily manufactured and maintains a high percentage of pharmaceutical activity and exhibits a high level of stability (column 4, lines 39-57)

With respect to claims 3-9, 15-20, there would be a reasonable expectation of success for one of skill in the art to obtain the IL-4R in the active monomeric form.

Therefore, the prior art references render obvious the instant claims.

Applicants argue that the Lange reference does not teach that there is any significant disadvantage or problem with administering IL-4R via a spray such that there is a suggestion or motivation to modify the reference or combine the reference with another. However, Applicants are arguing limitations that are not claimed. Instant claim 1 is drawn to "spray-dried particles comprising IL-4R". The Lange reference it being utilized in this rejection because it teaches an

IL-4R administered as a spray. If the Lange reference taught a "spray-dried composition comprising IL-4R", this rejection over Lange would be a 35 USC 102(b) rejection rather than a 35 USC 103 rejection.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Therefore, the prior art references render obvious claims 1-40.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
October 26, 2004